

November 18, 2002

K021501

**510(K) SUMMARY: V.A.C. Instillamat Device**

DEC 02 2002

**I. Name of Device:** V.A.C.® Instillamat Device

**II. Classification Name:** **Powered Suction Pump**  
**21 CFR 878.4780**

**III. 510(k) Applicant:** Kinetic Concepts, Inc. (KCI)  
8023 Vantage Drive  
San Antonio, TX 78265-8508  
Contact: Judith Harbour 1-800-275-4524

**IV. Substantial Equivalence:** V.A.C. Plus  
510(k) No.K992448  
Ambulatory V.A.C.  
510(k) No.K971548

**V. Description of Device**

The V.A.C. Instillamat device is a modified V.A.C. device manufactured by Kinetic Concepts Inc. The V.A.C. Instillamat device combines technologies and features of the V.A.C. Plus device previously cleared by the FDA in 1999 [510(k) No. K992448] and the Ambulatory V.A.C. device previously cleared by the FDA in 1997 [510(k) No. K971548] with the additional modifications to provide a controlled delivery system for applying secondary wound treatments to a wound.

**VI. Indications for Use**

The V.A.C. Instillamat device is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The V.A.C. is intended for patients with chronic, acute, traumatic, subacute and dehiscent wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

**VII. Substantial Equivalence**

The V.A.C. Instillamat device has essentially the same technologies and features as the previously cleared predicate devices and has been independently tested and successfully approved to the following medical safety standards:

- UL2601-1, The Standard for Safety of Medical Electrical Equipment, 1<sup>st</sup> Edition 1994
- IEC 60601-1-1, Medical Electrical Equipment - Part 1: General Requirements for Safety; 1. Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2, Medical Electrical Equipment - Part 1: General Requirements for Safety; 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-1-4, Medical Electrical Equipment - Part 1: General Requirements for Safety; 4. Collateral Standard: Programmable Electrical Medical Systems



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 02 2002

Kinetic Concepts, Inc.  
Judith Harbour  
Manager, Regulatory Affairs  
8023 Vantage Drive  
San Antonio, Texas 78265 - 9508

Re: K021501

Trade/Device Name: Vacuum Assisted Closure Instillamat  
Regulation Number: 878.4780  
Regulation Name: Powered suction pump  
Regulatory Class: Class II  
Product Code: JCX  
Dated: August 31, 2002  
Received: September 3, 2002

Dear Ms. Harbour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Judith Harbour

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Miriam C. Provost*  
for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K021501

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510(k) Number (if known): K021501

Device Name: **V.A.C. Instillamat®**

**Indications For Use:**

The V.A.C. Instillamat device is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The V.A.C. is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over-The-Counter  
Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K021501